

Lambert, Jason

From: Lambert, Jason
Sent: Friday, December 09, 2016 11:41 AM
To: Shannon, Teresa
Subject: Re: p-CBSA post editing

Teresa,

I left you a VM already so when you get a chance I would like you to give me a ring (859-689-4139). The p-CBSA files look just fine to me. As for the leftover comments in the assessment, I gave them a look. Rather than trying to create yet another track changes copy with my responses I thought I would provide input here. There was a question about display of units in Table 3A. My understanding is that our pro-forma structure implies universal application of mg/kg-day (for oral) throughout every entry in that section unless otherwise noted. Thus this is why the lead row reads "1. Oral (mg/kg-d)". This means all numbers are in this unit except for the one entry where it was only mg/kg; this was because this was the unit reported in the original study and due to a lack of information regarding study design or dosing schedule we cannot presume that it was repeated every day for 7 months. Lastly, as for the "highest-dose" terminology, it looks like we have them all correct now. If there are any further clarifications or questions on this one let me know. Thank you

From: Shannon, Teresa
Sent: Friday, December 9, 2016 10:50:26 AM
To: Lambert, Jason
Subject: Fw: p-CBSA post editing

Jason,

Please take a quick look at the attached files and let me know if there are any other changes that you want made before this starts clearance with Beth. It looks like the STSC would like us to double check the changes they made on the "high-dose" language. Thanks.

Teresa

From: Toms, Jacklyn
Sent: Friday, December 9, 2016 10:46 AM
To: Shannon, Teresa; CI NCEA STSC
Subject: RE: p-CBSA post editing

Teresa,

The p-CBSA clearance materials have been processed and are attached. There are a few track changes left in the PPRTV document where we changed high-dose to specify which dose group was being discussed. We were not entirely sure if all instances of "high-dose" were meant to be changed, or only some of them, so we left the changes for the author to review. There are also comments in Table 3A on pages 7-8 regarding missing units for values within the table.

In the developmental history, from a reader's perspective, we were worried that someone may look at the document only for subchronic information (section A) and miss the IR/ER comments in the chronic section (B), so, we duplicated the IR/ER comment tables and added a footnote explaining that the same information was used to derive the chronic/subchronic p-RfD values for clarity.

The rec memo is clean. A redline from the most recent ERD to CD1 is also included. Please let us know if there are any questions. We will bring you the hard copies.

Thanks,
Jacki

From: Shannon, Teresa
Sent: Thursday, December 08, 2016 8:57 AM
To: CI NCEA STSC <CI_NCEA_STSC@epa.gov>
Subject: FW: p-CBSA post editing

Please process this as the clearance draft. Let me know if you have any questions. Thanks.

Teresa Shannon
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Please consider the environment before printing this e-mail

From: Lambert, Jason
Sent: Wednesday, December 07, 2016 11:16 AM
To: Shannon, Teresa <Shannon.Teresa@epa.gov>
Subject: p-CBSA post editing

Good morning Teresa,
A huge thank you to the folks in STSC for the careful review/edit of the p-CBSA materials. They did a really good scrub and it is appreciated. I have attached some revised files to be processed for clearance review. The reconciliation memo and the document development history are clean versions not needing any further attention, that I can tell. I would like to note that STSC made a recommendation for the comments table in the doc development history (e.g., comments table should appear after the subchronic and chronic p-RfD tables). I consulted with Phillip on this topic. We agreed that since the subchronic and chronic screening p-RfDs were based on the exact same information/POD, and since the internal and external review comments were directed at the p-RfDs collectively (i.e., no subchronic vs. chronic specific comments) we decided to only provide the comments table one time following the chronic p-RfD derivation development table. I have also attached the PPRTV assessment with response to comment bubbles and a few associated edits for STSC consider when processing this for a clean clearance rev copy. Let me know if there are any questions in moving these materials forward. Thank you

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